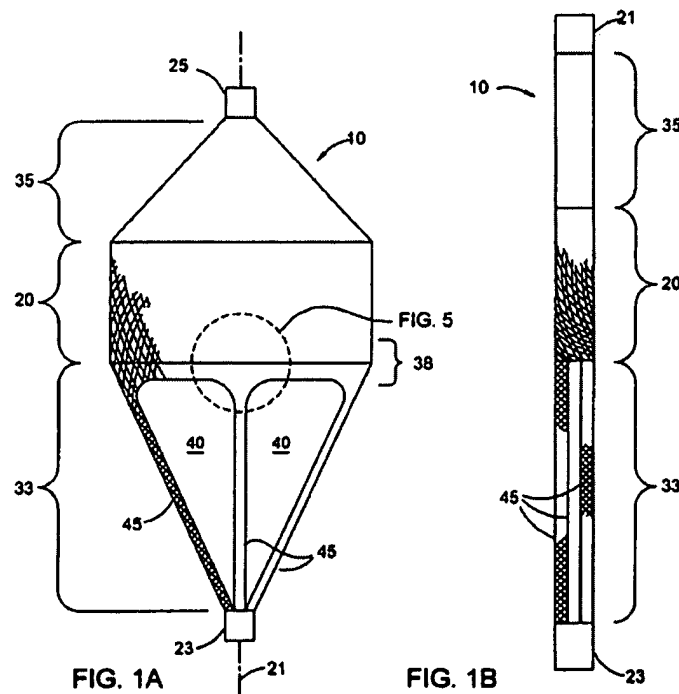


REMARKS/ARGUMENTS

This is in response to the official action of October 5, 2007. By the foregoing amendments the claims define that the intra-braided strands extend the full length of the proximal section of the filter. The claims are allowable for the reasons discussed below.

APPLICANTS' INVENTION

Applicants' invention relates to a construction of a temporary intraluminal vascular filter for capturing and removing emboli from a blood vessel during an interventional vascular procedure. The filter is formed from braided filaments and is illustrated in its expanded, deployed configuration and its collapsed configuration in FIGS. 1A and 1B, respectively, reproduced below.



The filter includes a cylindrical filter body 20 adapted to expand against the inner wall of the patient's vessel, a tapered distal section 35 and a tapered proximal section 33. Proximal and distal end members 23, 25 are attachable to a delivery device such as a catheter or hollow wire-like shaft coupled to the filter proximal end 23 and a movable core wire coupled to filter distal

end 25. The filter may be expanded or contracted by push-pull operation of the shaft and core wire.

A significant objective of the invention is to provide an improved filter construction that reduces accumulation of embolic debris outside the filter on upstream, proximally facing surfaces, particularly between or about the inlet ports. As explained in the written description, such accumulation may allow debris to break free and escape past the filter as the filter is closed. The filter construction is adapted to reduce that risk while also providing enlarged inlet ports at the proximal end of the filter to maximize the entrapment of debris in a filter that is simple to manufacture, while also providing good structural integrity.

The filter is formed from two arrays of filaments including first array filaments 53 and second array filaments 63. The filaments 53 in the first array extend from the distal end 25 to a region of junction 38 of the filter body 20 and proximal section 33. Filaments 63 extend from the distal end 25 all the way to the proximal end 23 of the filter. The filaments 53 and 63 are braided together to form the distal section 35 and filter body 20. The filaments 53 in the first array are severed in the junction region 38. The filaments 63 in the second array extending from the juncture region to the proximal end are divided into two or more groups with each group forming a plurality of filaments that are intra-braided together to compose a narrow strand 45. The strands 45 are slender and have a small combined surface area with the space between the strands defining large inlet ports 40. The enlarged ports 40 enhance blood flow into the filter with reduced likelihood of particulate matter accumulating on the external surfaces of the slender braided strands 45. The braided construction of the strands enhances the structural integrity of the device and extend the full length of the proximal section 33.

CITED PRIOR ART

U.S. Patent 6,375,670 (Greenhalgh)

Greenhalgh discloses a braided intraluminal filter as illustrated in FIG. 3, reproduced below.

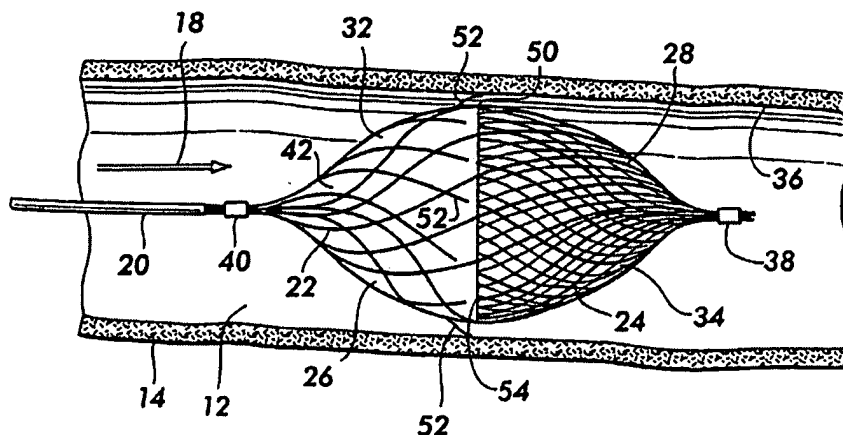


FIG. 3

The filter is formed from braided wires 22 and polyester yarns 24 arranged to define a distal filter element 28 that includes the braided metal wires 22 and polyester yarns 24. The proximal portion of the filter includes only the braided metal wires 22 that define entrance openings 42 to allow flow into the filter (4:61-65; 6:34-40). The braided pattern of the metal wires appears to be the same in the distal portion as the proximal portion.

U.S. Patent 6,336,934 (Gilson)

Gilson '934 discloses a variety of embolic protection devices with the device shown in FIG. 39 indicated in the action as being relevant. FIG. 39 is reproduced below.

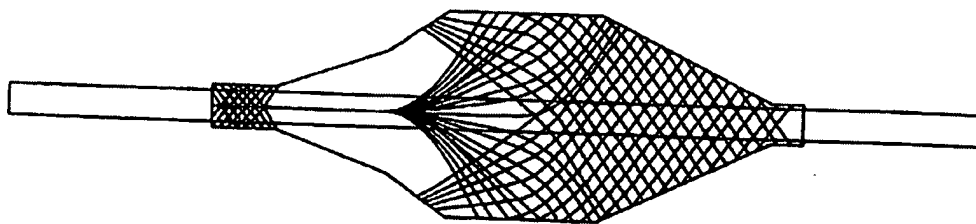


FIG. 39

FIG. 39 is described as showing "...a fibrous mesh filter design with fibers woven at the distal end and converging into a number of bundles at the proximal end;" (8:46-48). Elsewhere, at 6:42-47, Gilson states that "Larger proximal inlet holes are provided by the convergence of the

fibers of the braid into a few bundles which are mounted to the filter carrier.” Although it is not clear whether the column 6 statement is intended to refer to the FIG. 39 embodiment, these are the only parts of the written description that appear to relate to the embodiment in FIG. 39. The figure has no reference numerals and there is no further discussion in the written description.

U.S. Patent 6,346,116 (Brooks)

Brooks ‘116, in FIG. 5, discloses a filter arrangement that includes a filter 92 that “...can be formed from urethane material by adding salt, sugar or other granular particles during the casting of the urethane filter.” (3:64-67; 4:52-53). The filter 92 is associated with a frame formed from helical members 88 that are attached to and extend from a sinusoidal ring 84 adjacent the filter material. The device is deployed by advancing it to the deployment site while it is covered with a sheath and then withdrawing the sheath to allow the frame to resume its unrestrained position with the filter expanding to fill the cross-sectional area of the vessel. (5:9-17).

CLAIM REJECTIONS – 35 U.S.C. §103

The §103(a) Rejections Are improper Because They Do Not Resolve and Articulate The Level of Skill That Was Applied

The rejections under 35 U.S.C. §103(a) are improper because they fail to resolve and articulate the level of ordinary skill in the art that was applied. One of the essential underlying factual elements that must be determined under the Supreme Court decisions of *Graham v. John Deere Co.*, 383 U.S. 1 (1966) and *KSR International v. Teleflex, Inc.*, 127 S. Ct. 1727, 82 USPQ2d 1385 (2007) is that the level of skill must be resolved. The action fails to indicate what level of skill was applied in the §103(a) rejections. That failure leaves insufficient basis to test the correctness of the rejection. The failure to articulate the level of skill is, itself, a basis for withdrawal of the rejection.

Claims 1-4 and 6-10

Reconsideration is requested of the rejection of claims 1-4 and 6-10 as unpatentable under 35 U.S.C. §103(a) in view of the combined disclosures of Greenhalgh '670 and Gilson '934. Claim 1 is directed to the arrangement of the filter having first and second arrays of filaments with the filaments of the two arrays being intra-braided to define the cylindrical body and adjoining distal section and with the filaments of the second array extending proximally beyond the filter body to define the proximal section. Claim 1 requires that the proximally extending filaments of the second array are formed into two or more strands in which each strand is intra-braided from a plurality of filaments of the second array and where the intra-braided strands extend from the proximal end of the cylindrical body to the proximal end of the filter.

As acknowledged in the office action of October 5, 2007, Greenhalgh does not disclose that the filaments of the second array are intra-braided to form two or more strands in the filter proximal section. That feature of applicants' invention is not disclosed by Gilson. Gilson says little more about FIG. 39 than that the fibers "...[converge] into a number of bundles at the proximal end;" (8:46-48) and that it results in "larger proximal inlet holes" (6:45-48). Neither the written description in Gilson nor FIG. 39 describes an arrangement in which strands are formed by braiding the filaments of two or more groups of filaments together. To the contrary, FIG. 39 appears to illustrate filaments that converge and, somehow, attach to a single filament that extends to the proximal end of the filter. While Gilson may be considered as disclosing the convergence of fibers, it does not disclose the configuration of the fibers after they have converged. Reference to the convergence of the fibers "into a few bundles" suggests that the fibers extend in parallel. FIG. 39 appears to disclose no more than converged groups of fibers and a single line connection between the point of convergence and the proximal end of the filter structure. The action provides no reason to conclude that the connection between the point of convergence and the proximal end of the filter would be braided configuration. To do so would necessarily be hindsight reasoning, using applicants' disclosure as a template. Only applicants disclose an arrangement of filaments in a second array that are braided into strands that extend fully to the proximal end of the filter structure.

Each of claims 2-4 and 6-10 depends directly or indirectly from claim 1 and is patentable over Greenhalgh and Gilson for the same reasons discussed above in connection with claim 1.

Claim 5

Reconsideration is requested of the rejection of claim 5 as unpatentable under 35 U.S.C. §103(a) in view of the combined disclosures of Greenhalgh, Gilson and Brooks '116. Brooks fails to disclose those features of applicants' invention that are missing from Greenhalgh and Gilson, as discussed above in connection with claim 1. As to the additional limitation in claim 5 that the retention member comprises an elastic encapsulating sleeve by which the filaments of the first array are coupled to the filaments of the second array, the action acknowledges that the combination of Greenhalgh and Gilson do not disclose that feature. While Brooks discloses a sinusoidal ring member 84, that ring is described as being part of the frame from which helical members 86 extend. The ring 84 does not, as called for by the claim, couple filaments of the first array to filaments of the second array. Indeed, Brooks fails to describe just what the function of the sinusoidal ring is. Additionally, the action fails to indicate where or how the sinusoidal ring 84 in Brooks serves as an encapsulating member, as claimed.

Claims 11-14

Reconsideration is requested of the rejection of claims 11-14 as unpatentable under 35 U.S.C. §103(a) in view of the combined disclosures of Greenhalgh, Gilson and Molgaard-Nielsen '246. As discussed above in connection with claim 1, Gilson does not disclose dividing unsevered filaments in the proximal filter section into two or more groups and then intra-braiding each group of filaments into a corresponding strand that extends fully to the proximal end of the filter. Where none of Greenhalgh, Gilson or Molgaard-Nielsen discloses this feature of applicants' invention, their combination cannot be considered as doing so.

Respectfully submitted,

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